

REMARKS

Summary of Office Action

As an initial matter, Applicants note with appreciation that a signed and initialed copy of the Form PTO-1449 submitted in the Supplemental Information Disclosure Statement filed July 6, 2006 has been returned together with the present Office Action.

Claims 37-43, 45-52 and 55-65 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Merkle et al., U.S. Patent No. 5,527,536 (hereafter "MERKLE") in view of Lucast et al. U.S. Patent No. 6,479,073 (hereafter "LUCAST I") in view of Koketsu et al., U.S. Patent No. 5,547,223 (hereafter "KOKETSU").

Claim 44 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU and further in view of Bodenschatz et al., U.S. Patent No. 6,074,965 (hereafter "BODENSCHATZ").

Claim 44 is also rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU and further in view of a newly cited document, i.e., Tomioka et al., U.S. Patent No. 4,722,857 (hereafter "TOMIOKA").

Claims 53 and 54 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU and further in view of another newly cited document, i.e., Fischer et al., U.S. Patent No. 5,863,977 (hereafter "FISCHER").

Claim 66 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU and further in view of yet another

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newly cited document, i.e., Kantner et al., U.S. Patent No. 5,489,624 (hereafter "KANTNER").

Claim 67 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU and further in view of Lucast et al., U.S. Patent No. 5,407,717 (hereafter "LUCAST II").

Claim 68 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU and further in view of yet another newly cited document, i.e., Cilento et al., U.S. Patent No. 5,059,189 (hereafter "CILENTO").

Claims 69-73, 75-82 and 85-95 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU in view of Wildeman et al., U.S. Patent No. 3,967,472 (hereafter "WILDEMAN").

Claim 74 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU in view of WILDEMAN and further in view of BODENSCHATZ.

Claim 74 is also rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU in view of WILDEMAN and further in view of TOMIOKA.

Claims 83 and 84 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU in view of WILDEMAN and further in view of FISCHER.

Claim 96 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU in view of WILDEMAN and further in view of KANTNER.

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Claim 97 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU in view of WILDEMAN and further in view of LUCAST II.

Claim 98 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over MERKLE in view of LUCAST I in view of KOKETSU in view of WILDEMAN and further in view of CILENTO.

Claims 37-52, 55-65, 69-82 and 85-95 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-27 of U.S. Patent No. 6,555,730 to Albrod et al. (hereafter "ALBROD") in view of MERKLE.

Claims 53-54 and 83-84 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-27 of ALBROD in view of MERKLE and further in view of FISCHER.

Claims 66 and 96 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-27 of ALBROD in view of MERKLE and further in view of KANTNER.

Claims 67 and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-27 of ALBROD in view of MERKLE and further in view of LUCAST II.

Claims 68 and 98 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-27 of ALBROD in view of MERKLE and further in view of CILENTO.

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested in view of the following remarks.

Response to Rejection of Claims under 35 U.S.C. § 103(a) over MERKLE in View of LUCAST I in View of KOKETSU

Applicants note that all claim rejections under 35 U.S.C. § 103(a) set forth in the present Office Action are based on at least MERKLE in view of LUCAST I in view of KOKETSU. In this regard, the rejection alleges that MERKLE “discloses that the backing layer may be a polyester film (see Examples) but is silent with regards to specific polyester film structures” wherefore “it would have been necessary and thus obvious to look to the prior art for conventional backing layer structures”.

The rejection further alleges that LUCAST I “provides this conventional teaching showing that it is known in the art to use a nonwoven backing layer overstitched with yarns”. The rejection concedes that LUCAST I does not mention how many stitches (per cm) are present on the backing layer, but asserts that KOKETSU discloses that it is known in the art that the number of stitches is a result effective variable that would alter the strength of the web, wherefore it would allegedly have been obvious to one of ordinary skill in the art “to provide 5 to 50 longitudinal stitches per cm in order to create a stitch-bonded fabric with a desired strength and rigidity”.

Applicants respectfully submit that this rejection is without merit for various reasons. Specifically, it is not correct that MERKLE “is silent with regards to specific polyester film structures”. On the contrary, it appears that each of the Examples of MERKLE specifies not

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only the thickness of the polyester film which is used as backing layer, but additionally specifies the thickness of the (second) polyester film which is silicone-coated and serves as a removable protective layer. In this regard, col. 6, lines 1-10 of MERKLE may, for example be referred to.

For this reason alone and additionally in view of the fact that in all of the numerous Examples of MERKLE a polyester film is employed as backing layer, one of ordinary skill in the art would not have been motivated at all to look for materials which can replace the polyester film of MERKLE. However, even if one were to share, *arguendo*, the Examiner's position that one of ordinary skill in the art would have been motivated "to look to the prior art for conventional backing layer structures", this would not amount to a motivation to replace the polyester film of MERKLE with any other conventional backing material structure.

Further, even if one were to assume, *arguendo*, that one of ordinary skill in the art would have been motivated (for some unknown reason) to replace the polyester film of MERKLE with any other conventional backing material structure, it is not seen what would have motivated one of ordinary skill in the art to pick and choose an overstitched nonwoven from the numerous types of backing materials disclosed by LUCAST I, i.e., a material that is neither particularly recommended by, nor used in any of the Examples of LUCAST I. In fact, it appears that the backing materials employed in the 81 exemplary articles of LUCAST I are exclusively polyester films, polyurethane films or polyurethane blown microfiber backings.

It even would appear that the fact that polyester films are employed in several of the exemplary articles of LUCAST I can be considered to be an independent confirmation that

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polyester films are a good choice for the backing materials of the laminate of MERKLE. In other words, this fact would appear to be a disincentive rather than a motivation for one of ordinary skill in the art to replace the polyester film of MERKLE by any other (conventional) backing material.

Still further, there is even at least one reason why one of ordinary skill in the art would be discouraged from using any nonwoven as replacement for the polyester film backing material of MERKLE: According to MERKLE, the active substance that is to be incorporated into the pressure-sensitive adhesive is a substance which, at the temperature at which the adhesive bonds, is a readily volatile liquid (see, e.g., Abstract of MERKLE). It would be immediately apparent to one of ordinary skill in the art that when using a nonwoven instead of a (polyester) film as backing material for the self-adhesive matrix of MERKLE there would be a substantially higher risk for the active substance to evaporate through and/or ooze out of the backing material during use and/or storage of the laminate. (This is likely also the reason why the removable protective layer of the laminate of MERKLE is a polyester film as well.)

Applicants respectfully submit that for at least all of the foregoing reasons, one of ordinary skill in the art would not have been motivated to replace the polyester film of MERKLE by any other backing material, let alone by a nonwoven backing material. Accordingly, MERKLE in view of LUCAST I does not render it obvious to provide a (any) nonwoven backing material with a (any) adhesive hot melt composition comprising at least one pharmacologically active substance incorporated therein.

Even if one were to assume, *arguendo*, that all of the facts set forth above can be ignored and that one of ordinary skill in the art would be motivated to replace the polyester

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film of MERKLE by an overstitched nonwoven, it is not seen why one of ordinary skill in the art would have been motivated to use a nonwoven that is overstitched by yarns with a number of stitches of at least 3/cm of web as it is recited in the present independent claims.

Applicants note that in this regard the rejection relies on column 7, lines 16-32 of KOKETSU which allegedly discloses “that it is known in the art that the number of stitches is a result effective variable that would alter the strength of the web, with more stitches supplying a stronger web”.

This argument is respectfully traversed as well. Specifically, KOKETSU constitutes non-analogous art in that it does not relate to any article for use in medicine, let alone to an article for application to the skin, but to a webbing for restraining a vehicle occupant such as a safety belt (see, e.g., front page of KOKETSU).

Further, KOKETSU relates to a webbing, i.e., not to a nonwoven material.

Even further, even the passage of KOKETSU which is relied on in the rejection, i.e., column 7, lines 16-32 does not appear to mention the number of stitches per unit of length, let alone in the context of strengthening the webbing. All that is mentioned in this passage is the number and length of stitch rows, i.e., not the number and/or length of stitches.

The facts set forth above constitute additional reasons as to why the present claim rejections under 35 U.S.C. § 103(a) over MERKLE in view of LUCAS I in view of KOKETSU are unfounded and should be withdrawn, which action is respectfully requested.

Response to Rejection of Claims under 35 U.S.C. § 103(a) over MERKLE in View of LUCAST I in View of KOKETSU and Further in View of an Additional Document

Applicants submit that in view of the fact that all claim rejections under 35 U.S.C. § 103(a) set forth in the present Office Action are based on at least MERKLE in view of LUCAST I in view of KOKETSU and that this rejection is without merit for at least all of the reasons set forth above, there appears to be no need to comment on each and every rejection of a dependent claim which is based on the aforementioned documents and at least one additional document, i.e., at least one of BODENSCHATZ, TOMIOKA, FISCHER, KANTNER, CILENTO, WILDEMAN and LUCAST II. Accordingly, only a few of the remaining rejections and allegations set forth in the present Office Action will be addressed in the following.

Applicants emphasize that they do not concede by any means that any of the rejections and allegations set forth in the present Office Action which is not addressed below is meritorious.

1. At page 4, first full paragraph of the present Office Action it is alleged that “considering that the backing material taught by the applied prior art is substantially identical to the claimed backing material (stitch-bonded polyester nonwoven with 5-50 stitches per cm), it appears that the backing material inherently possesses the claimed properties”. Applicants fail to see where in the prior art a backing material which is substantial identical to the claimed backing material is taught and neither does the present Office Action contain any indication in this regard.

2. At page 4, last paragraph of the present Office Action it is alleged that “the amount of adhesive is a result effective variable that would affect the degree of adhesion

the tape would have to the skin". Applicants fail to see where in the prior art it is disclosed that the amount of adhesive is a result effective variable that would affect the degree of adhesion. It would appear that in the case of a backing material of the type recited in the present claims, complete coverage of one side of the web with adhesive is sufficient for achieving optimum adhesion to the skin and that any amount of adhesive that exceeds the amount that is necessary for complete coverage will not significantly increase the degree of adhesion.

3. At page 6, second paragraph of the present Office Action it is stated that the polyester film of MERKLE is "considered to read on the claimed wound pad". Applicants fail to see how a polyester film having a thickness of the order of 100 μm (0.1 mm) can be considered to be a wound pad.

4. At page 9, second paragraph of the present Office Action it is alleged that MERKLE "appears to be silent with regards to specific pharmacologically active substances, therefore, it would have been necessary and thus obvious to look to the prior art for conventional pharmacologically active substances".

Applicants respectfully submit that MERKLE is not silent with regard to specific pharmacologically active substances that are to be incorporated into the self-adhesive matrix disclosed therein. For example, in col. 4, lines 21-26, MERKLE specifies the active substances as "low-melting and/or volatile active ingredients, especially of nicotine and of β -receptor blockers, such as bupranolol". Nicotine and bupranolol are also the active substances which are employed in the Examples of MERKLE.

In view of the foregoing, it would not have been necessary for one of ordinary skill in the art "to look to the prior art for conventional pharmacologically active substances",

contrary to what is alleged in the present Office Action.

Response to Obviousness-Type Double Patenting Rejection

Claims 37-98 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of ALBROD in view of MERKLE, either alone or in view of one of FISCHER, KANTNER, CILENTO and LUCAST II.

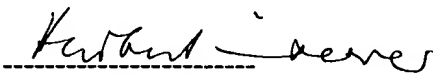
Applicants respectfully request that these rejections be held in abeyance until the Examiner has indicated allowable subject matter. Thereafter, Applicants will decide whether the filing of a Terminal Disclaimer is appropriate.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
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